

July 20, 2020

Via E-Mail: AGO.highcostprescriptiondrugs@vermont.gov

Re: New Drug Introduction Report Pursuant to 18 V.S.A. §4637(c)

To the Office of Attorney General:

On July 1, 2020, Ultragenyx Pharmaceutical ("Ultragenyx") introduced the following drug into the market:

NDC Number	Drug Product Description
69794-0050-50	Dojolvi .96g/mL, 500mL in 1 bottle

Pursuant to 18 V.S.A. §4637(c), Ultragenyx provides the following additional product information listed below.

1. US and international marketing and pricing plans used at launch
 - a. Because this information is not in the public domain or publicly available and is confidential, Ultragenyx declines to provide this information in accordance with 18 V.S.A. §4637(d).
2. Estimated volume of patients
 - a. The estimated number of patients who may be prescribed Dojolvi is not in the public domain, not publicly available, and is confidential, Ultragenyx declines to provide this information in accordance with 18 V.S.A. §4637(d).
 - b. Ultragenyx does not have any information on the estimated volume of patients.
3. Whether the FDA granted breakthrough therapy designation or priority review
 - a. Priority review was granted by the FDA.
 - b. Breakthrough therapy designation was not granted.
4. Date and price of acquisition
 - a. Ultragenyx did not acquire the product from another manufacturer.

Please feel free to contact me if you have any questions and/or require any additional information.